

Appl. No. 10/025,668

AmdtAF dated January 14, 2005

Reply to final Office Action of November 17, 2004

### REMARKS

Applicants have carefully reviewed the Final Office Action dated November 17, 2004, prior to preparing this response. Currently, claims 1-35 are pending in the application, wherein claims 1-35 are rejected by the Examiner. Claim 20 has been amended with this reply. Applicants respectfully traverse all rejections and assertions made by the Examiner and request favorable consideration of the above amendment and following remarks prepared in view of the rejections.

Reasserting the request acknowledged in the previous response, Applicants again wish to bring to the Examiner's attention that formal drawings were submitted on December 18, 2001, but there has been no indication of approval of the drawings by the Examiner or the Official Draftsman. Applicants renew their request that the Examiner/Official Draftsman indicate approval or non-approval of the formal drawings with the next PTO communication.

Claim 20 has been amended with this response to recite that the polymer jacket comprises a shape memory polymer. Applicants assert this limitation already existed in claims depending from claim 20, and claim 20 is amended to provide proper antecedent basis in compliance with the requirements of 35 U.S.C. §112, Second Paragraph. Applicants respectfully request entry of this amendment, asserting amendments complying with requirements as to form may be permitted after final action in accordance with 37 CFR §1.116(b). Additionally, Applicants respectfully assert an amendment that will place the application either in condition for allowance or in better form for appeal may be entered after Final rejection. See M.P.E.P. §714.12. Applicants request the Examiner enter the proposed amendment to claim 20, asserting the amendment does not raise the issue of new matter or present new issues requiring further consideration or search. Applicants believe the amendment places the claim in condition for allowance, or otherwise places the claim in better form for subsequent appeal.

Claims 1-4 and 20-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dubrul (U.S. Patent No. 5,944,701). Applicants respectfully traverse this rejection, asserting that these claims are indeed allowable over Dubrul. In order to anticipate, a prior art reference must disclose each and every element of the claimed invention. See M.P.E.P. §2131. Applicants assert Dubrul fails to teach every element of the invention as claimed in the rejected claims.

Claim 1 recites:

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An intravascular guidewire comprising:  
an elongate core wire comprising a metal; and  
a polymer jacket comprising a shape memory polymer attached to and  
surrounding a portion of the core wire, the polymer jacket being more stiff than  
the portion of the core wire which it surrounds.

Applicants assert that not only must the prior art reference include every element of the claimed invention, but the invention must be shown in as complete detail as is contained in the claim and the elements must be arranged with all the structural limitations provided in the claim. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989); *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Applicants assert Dubrul fails such an evaluation.

Dubrul teaches a guidewire preferably formed from a shape memory alloy. See column 2, lines 56-60. Alternatively, the guidewire may be formed from known shape memory polymers or a shape memory polymer with a shape memory metal alloy coating. See column 3, lines 45-48. In other words, the only guidewire taught by Dubrul having a metallic portion and a shape memory polymer portion appears to be that of a shape memory polymer core and a shape memory alloy coating. Hence, Applicants assert at no point does Dubrul teach a guidewire including a core wire comprising a metal and a polymer jacket comprising a shape memory polymer as currently claimed. The Examiner asserts Dubrul discloses "a polymer jacket attached to and surrounding a distal portion of the core wire" at column 3, lines 38-39. Applicants assert the Examiner's interpretation of the teachings of Dubrul is in error. Although Dubrul teaches covering a guidewire formed from shape memory alloys with a polymeric coating, this is not what is claimed in Applicants' claim 1. Namely, claim 1 includes a polymer jacket comprising a shape memory polymer. As asserted above, the prior art reference must disclose the invention in as complete detail as contained in the claim. "A genus does not always anticipate a claim to a species within the genus." M.P.E.P. §2131.02. Applicants assert properties of a shape memory polymer are distinct to those of other polymers. The unique properties of the shape memory polymers of the polymer jacket may provide shaping and/or forming capabilities not offered with other polymers. Dubrul fails to teach a polymer jacket comprising a shape memory polymer. At least because Dubrul fails to disclose a shape memory polymer jacket, Applicants assert Dubrul fails to anticipate claim 1. Applicants request withdrawal of the rejection, asserting claim 1 is

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currently in condition for allowance. Claims 2-4 depend from claim 1 and contain significant additional limitations; therefore, they also are believed to be in condition for allowance.

Claim 20 includes limitations similar to those discussed above regarding claim 1, as well as additional limitations. As stated above, in order to anticipate, a prior art reference must disclose the identical invention in as complete detail as is contained in the claim. See M.P.E.P. §2131; *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). For at least the reasons stated above regarding claim 1, Applicants assert Dubrul fails such an evaluation as to claim 20. Contrary to the Examiner's assertions, Dubrul at least fails to teach a guidewire comprising a metallic core wire and a shape memory polymer jacket attached to and surrounding a distal tip portion of the core wire. Therefore, claim 20 is believed to be in condition for allowance. Claims 21-23 depend from claim 20 and add significant additional elements; therefore, they are also believed to be in condition for allowance.

Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Gunatillake et al. (WO 01/07499). Applicants respectfully traverse this rejection, asserting a *prima facie* case has not been established. Claim 17 recites a method of shaping a guidewire, wherein the guidewire comprises an elongate core wire with a shape memory polymer jacket attached to and surrounding a portion of the core wire. As discussed above, Dubrul fails to teach a guidewire with the structural limitations of the guidewire of claim 17. Applicants respectfully assert Gunatillake fails to remedy the shortcomings of Dubrul. Therefore, at least because not every element of the claimed invention is either taught or suggested by the prior art references, Applicants assert a *prima facie* case of obviousness has not been established. See M.P.E.P. §2143.03. Therefore, claim 17 is believed to be in condition for allowance and withdrawal of this rejection is requested.

Claims 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Lafontaine (U.S. Patent No. 5,662,621). Applicants respectfully traverse this rejection, asserting a *prima facie* case has not been established. Notwithstanding the fact that Lafontaine is nonanalogous art and there is no motivation to combine the teachings of Dubrul with those of Lafontaine, Applicants assert each and every element of the claimed invention is not disclosed by the combination of references required to establish a *prima facie* case of obviousness.

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Claim 17 recites a method of shaping a guidewire, wherein the guidewire comprises an elongate core wire with a shape memory polymer jacket attached to and surrounding a portion of the core wire. Neither Dubrul nor Lafontaine teach a shape memory polymer jacket attached to and surrounding a portion of a core wire. The deficiencies of Dubrul are presented in sufficient detail above. Lafontaine teaches a guide catheter with shape memory retention. The core 24 taught in Lafontaine is not a core wire as in the present invention. Lafontaine fails to teach a shape memory jacket attached to and surrounding a core wire. Applicants assert the prior art must teach the claimed invention in as much detail, including all structural limitations, as provided in the rejected claim. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989); *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Lafontaine "discloses an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a different way." *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). An analysis treating the claims as "mere catalogs of separate parts," while disregarding the "part-to-part relationships set forth in the claims" is impermissible. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Applicants assert the core 24 of the device taught in Lafontaine is not attached to the catheter shaft 22 and operates in a notably different way.

Additionally, there is no motivation to modify the device of Lafontaine. Applicants assert that if a "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. §2143.01, citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As disclosed in Lafontaine, the core provides stimulus (thermal, chemical or light) to the guide catheter for transitioning the guide catheter between a soft, straight state and a pre-shaped, relatively stiff, memory retention state. See column 5, lines 60-62. Once the guide catheter is positioned in the body, the core may be removed to allow completion of the catheterization procedure. See column 7, lines 23-28. Applicants assert treating the catheter shaft 22 as a polymer jacket and attaching the catheter shaft 22 to and surrounding the core 24 would render the Lafontaine invention nonfunctional and unsatisfactory for its intended purpose. If the catheter shaft were attached to the core, then the core would not be removable from the

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catheter shaft and a subsequent catheterization procedure could not be completed, thus making the device unsatisfactory for its intended purpose. Therefore, there is no motivation to modify Lafontaine as the Examiner suggests in combining the references.

Applicants assert, at least because each and every element of the claimed invention is not taught by the combination and there is no motivation to combine the references, a *prima facie* case of obviousness has not been established with the combination of references. Applicants assert claim 17, and therefore claims 18 and 19, are currently in condition for allowance and withdrawal of the rejection is requested.

Claims 5-16 and 24-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Takahashi (U.S. Patent No. 6,485,458). Claims 5-16 depend from claim 1 and claims 24-35 depend from claim 20. Therefore, for the reasons stated above concerning the allowability of claims 1 and 20, Applicants respectfully assert this rejection is moot.

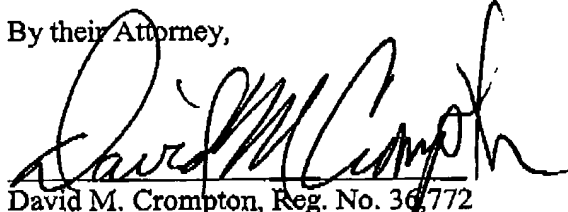
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Stephen Griffin et al.

By their Attorney,

Date: 1/14/05



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